REMARKS:

Applicant has carefully studied the nonfinal Examiner's Action and all references cited therein. The amendment appearing above and these explanatory remarks are believed to be fully responsive to the Action. Accordingly, this important patent application is now believed to be in condition for allowance.

Applicant responds to the outstanding Action by centered headings that correspond to the centered headings employed by the Office, to ensure full response on the merits to each finding of the Office.

<center>Claim Rejections – 35 U.S.C. § 112</center>

Applicant acknowledges the quotation of 35 U.S.C § 112, second paragraph.

Claims 1-12 stand rejected under 35 U.S.C § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 has been amended to more clearly describe that which the applicant regards as the invention. Applicant believes that the amendment presented to the claims is sufficient to overcome the 35 U.S.C § 112, second paragraph, rejection.

<center>Claim Rejections – 35 U.S.C. § 102</center>

Applicant acknowledges the quotation of 35 U.S.C § 102(e).

Claims 1-5, 9, 10 and 12 stand rejected under 35 U.S.C § 102(e) as being anticipated by Huo et al. (U.S. Patent No. 6,282,305).

The Office states that Huo et al. discloses a method which includes establishing a risk probability with a patient with factors such as age (column 5, lines 55-63); applying a computer algorithm to find abnormalities in a patient's mammogram (column 9, 30-48); changing the tolerance level for high risk and low risk patients (differentiating the patterns among high risk and low risk patients (column 8, line 61- column 9, line 7).

<center>5</center>

Applicant respectfully traverses the finding of the Office.

The present invention determines a breast cancer risk probability value for a patient based on a set of risk factors. A computer algorithm them analyzes a patient's mammogram based on a standard threshold for false positive abnormalities. The standard threshold has an associated tolerance level. The present invention then applies the risk probability value to the computer algorithm analysis and adjust the threshold for identifying false positive abnormalities such that the threshold is higher for a patient identified as being at a low risk for breast cancer based on the risk factors and the threshold is lower for a patient identified as being at a high risk for breast cancer based on the risk factors.

Huo et al. does not describe the method of the present invention in which the threshold of the computer algorithm for identifying false positive abnormalities is adjusted such that the threshold is higher for a patient identified as being at a low risk for breast cancer based on the risk factors and the threshold is lower for a patient identified as being at a high risk for breast cancer based on the risk factors.

The office contends that this method step is taught by Huo et al. beginning at column 8, line 61, where in Huo describes, "differentiating the patterns among high risk and low risk patients". This description is not equivalent to the adjustment of the threshold value as disclosed and claimed by the present invention.

Huo et al. describes the classification of BRCA1/BRCA2 mutation carriers and "low-risk" women in more detail beginning at column 16. It is clear from this descriptive detail that the method described by Huo utilizes the extracted mammogram features to discriminate between high risk and low risk patients. The objective of Huo is to be able to identify a set of features that can be extracted from a mammogram that can distinguish a patient that is a BRCA1/BRCA2 mutation carrier from a patient that is not a carrier. Huo can therefore distinguish a high risk patient (i.e. BRCA1/BRCA2 mutation carrier) from a low risk patient based on the mammogram features without the need for genetic testing. Huo does not describe adjusting the threshold for the computer algorithm mammogram based on the risk factors, but rather he is using known risk factor methods (i.e. BRCA1/BRAC2 carrier, Gail Model, Claus Model) to establish a correlation between these risk factor methods and the analysis of extracted

6

mammogram features.   As described in the Abstract, features extracted from a patient's mammogram are compared against predetermined models of patterns based on risk factors, such as gene carrier information or clinical information, to determine the risk of breast cancer. This is not equivalent to the method as described and claimed by the present invention.

Claims 1, 6-9, 10 and 11 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Wang (U.S. Patent No. 6,266,435).

Regarding claim 1, the Office states that Wang discloses establishing a risk probability value from risk factors (such as the pattern of the mammogram) (column 4, lines 17-38); applying a computer algorithm adapted to find abnormalities (column 7, lines 10-37); increasing or decreasing the tolerance rate for false positives in relation to the probability value (column 8, line 14 – column 9, line 7).

Applicant respectfully traverses the finding of the Office.

The method described by Wang is a means to assign probability values to patterns identified on a mammogram that are believed to be cancerous. The purpose of assigning and displaying these probability values on the mammogram is to give the radiologist a way to prioritize his/her analysis of the mammogram. So, if an area of the mammogram is identified by the CAD program as having a high probability of being cancerous, the radiologist would focus on this area before looking at an area that is classified as having a low probability of being cancerous. These probabilities are based on adjustable threshold levels of the CAD system.

The present invention discloses and claims a risk probability value associated with a patient, not a risk probability value of a pattern of a mammogram as the claims has been interpreted by the Office. The risk probability value associated with a patient as disclosed and claimed by the present invention is calculated from an array of risk factors. These factors may include at least one factor selected from a group of factors including age, racial background, geographic background hormonal data, breast size, weight and height, pregnancies, breast surgeries, breast water content, transverse relaxation time, family medical history, previous biopsies, length of reproductive years, menopausal status, parity, age of menarche, age of menopause, involution characterization, density time dependency, density dependent texture,

7

dietary factors, abnormality spatial location and physical activity. Wang does not describe the probability risk value of the patient in accordance with the present invention. Accordingly, Wang does not describe adjusting the threshold level of the computer algorithm in response to the risk probability value of the patient as claimed by the present invention.

For the reasons cited above, Applicant believes that amended independent claim 1 is not anticipated by Huo et al. or by Wang, and is believed to be in condition for allowance.

Claims 2-12 are dependent upon claim 1, and are therefore allowable as a matter of law.

If the Office is not fully persuaded as to the merits of Applicant's position, or if an Examiner's Amendment would place the pending claims in condition for allowance, a telephone call to the undersigned at (727) 507-8558 is requested.

Very respectfully,

SMITH & HOPEN

By:_____
Dated: September 14, 2005   Molly Sauter
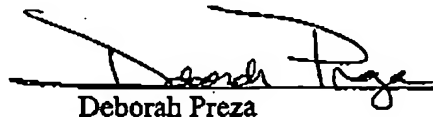   15950 Bay Vista Drive, Suite 220
                                             Clearwater, FL 33760
                                             (727) 507-8558
                                             Attorneys for Applicant

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CERTIFICATE OF FACSIMILE TRANSMISSION
(37 C.F.R. 1.8(a))

I HEREBY CERTIFY that this Amendment A is being transmitted by facsimile to the United States Patent and Trademark Office, Art Unit 1631, Attn: Jerry Lin, (571) 273-8300 on September 14, 2005.

Dated: September 14, 2005

Deborah Preza

8